1. Name, Address of Contact Person

JUL 15 2011

Applicant's name and address

Astoria-Pacific, Inc.
FDA Establishment No. 3050015
15130 SE 82nd Drive
P.O. Box 830
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Tel 1-503-657-3010
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Charles A. Peterson
President

Jason Reynolds
Director of R & D, Official Correspondent

2. Name of the Device

Product Classification

Reagent Kit

Regulation Number	21 CFR 862.1315
510(k) Number	k102643
Classification Panel	Clinical Chemistry
Product Code	KQP
Device Classification	Class II

Product Nomenclature

Common Name	GALT (Galactose-1-phosphate uridyl transferase) Screening Test
Classification Name	Galactose-1-phosphate uridyl transferase test system
Proprietary Name	Astoria-Pacific SPOTCHECK® Neonatal GALT Microplate Reagent Kit - 60 Plate
Model Number	Astoria-Pacific Part No. 81-4000-60K

Instrument

Regulation Number	21 CFR 862.2300
510(k) Number	k102643
Classification Panel	Clinical Chemistry
Product Code	JJQ
Device Classification	Class I

Product Nomenclature

Common Name	Photometer for clinical use
Classification Name	Colorimeter, photometer, spectrophotometer for clinical use
Proprietary Name	SPOTCHECK Pro™
Model Number	Astoria-Pacific Part No. 910-0500-00

3. Identification of the legally-marketed device for which substantial equivalence is claimed.

Product Classification

Reagent Kit

Regulation Number	21 CFR 862.1315
510(k) Number	K990827
Classification Panel	Clinical Chemistry
Product Code	KQP
Device Classification	Class II

Product Nomenclature

Common Name	GALT (Galactose-1-phosphate uridyl transferase) Screening Test
Classification Name	Galactose-1-phosphate uridyl transferase test system
Proprietary Name	Bio-Rad Quantase Neonatal GALT Test
Model Number(s)	Bio-Rad Part No. 532-6000, 192 Test Kit Bio-Rad Part No. 532-6001, 960 Test Kit

Instrument

Regulation Number	21 CFR 862.2300
510(k) Number	K953710
Classification Panel	Clinical Chemistry
Product Code	JJQ
Device Classification	Class I

Product Nomenclature

Common Name	Photometer for clinical use
Classification Name	Colorimeter, photometer, spectrophotometer for clinical use
Proprietary Name	Bio-Tek ELX808 Automated Microplate Readers
Model Number(s)	Part No. ELX808IUAP

4. Description of the Device

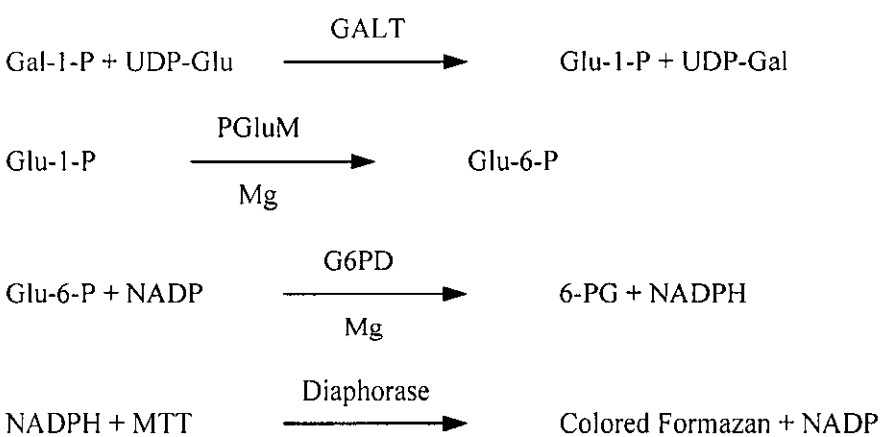
SPOTCHECK Neonatal GALT Microplate Reagent Kit - 60 Plate

Astoria-Pacific Part No. 81-4000-60K
Galactose-1-phosphate uridyl transferase test system

KIT CONTENTS:

Substrate
Color Reagent
Stock Standard
Tris Buffer

Four enzyme mediated reactions are employed in the determination of GALT activity. The GALT enzyme catalyzes the conversion of galactose-1-phosphate to glucose-1-phosphate and concurrently the conversion of UDP-glucose to UDP-galactose. Then, glucose-1-phosphate is converted to glucose-6-phosphate catalyzed by the enzyme phosphoglucomutase. Next, glucose-6-phosphate is oxidized to 6-phosphogluconate with the concurrent reduction of NADP to NADPH, catalyzed by glucose-6-phosphate dehydrogenase. Finally, a tetrazolium salt, catalyzed by diaphorase, reacts with the NADPH to form the product that is measured to yield GALT activity.



GALT activity is determined by measuring the colored formazan produced by the addition of the color reagent to the incubated blood/substrate mixture.

Patient samples of whole blood collected on standardized filter paper are placed into the wells of a standard 96 well microplate. A buffered enzyme mixture is added to each well and the plate is incubated at 37 °C for 120 minutes on a plate shaker/incubator. Following incubation, an aliquot of the mixture from each well is transferred to the corresponding wells on a clean 96 well microplate. Color reagent is added to each well, the color is developed over the course of 10 minutes, and the absorbance of each sample is

determined on the plate reader. A blank absorbance reading is made prior to the addition of the color reagent to correct for endogenous sample color.

The color developed is proportional (1:1) to the GALT activity in the sample. A standard curve prepared from a stock NADH solution is used to quantitate the results. Results are expressed as units of GALT enzyme activity per gram of hemoglobin or U/g Hb. A unit is defined as the quantity of GALT enzyme that catalyzes the formation of one micromole of UDP-galactose per minute at 37 °C.

SPOTCHECK Pro

Astoria-Pacific Part No. 910-0500-00
Galactose-1-phosphate uridyl transferase test system

INSTRUMENT COMPONENTS:

Tecan Freedom EVO® and accessories necessary for assay

5. Statement of Intended Use

The SPOTCHECK Neonatal GALT Microplate Reagent Kit is for the quantitative determination of galactose-1-phosphate uridyl transferase, EC 2.7.7.12 (GALT), activity in whole blood saturated filter paper disks, using a microplate absorbance reader. Measurements of galactose-1-phosphate uridyltransferase are used primarily in the diagnosis and treatment of the hereditary disease galactosemia. This method is intended for in vitro diagnostic use as an aid in newborn screening for decreased levels of GALT enzyme activity, and not for monitoring purposes.

The SPOTCHECK Pro is used for automated sample processing in the application of in vitro diagnostic assays. Specimens containing patient bodily substances are introduced and analyzed in microtiter plates using qualitative/quantitative determination through absorbance measurements.

These devices are intended for use by trained, qualified laboratory personnel.

6. Summary of the Technological Characteristics of the Device

DEVICE COMPARISON

The most significant difference between the SPOTCHECK Neonatal GALT Microplate Reagent Kit and the predicate device is the use of a calibration curve with the SPOTCHECK Kit to quantify results. Additionally, the SPOTCHECK Kit is also intended for use on automated platforms. Both the proposed and predicate devices use approximately the same reagent formulation and both use the same technology (spectrophotometric microplate reader) to determine GALT activity.

Neonatal patient dried blood specimens are punched into microplate wells, eluted and incubated with approximately the same substrate and buffer system on the SPOTCHECK Kit as on the predicate device. On the SPOTCHECK Kit, the tetrazolium salt (MTT) is not introduced into the reagent scheme until the final chemical reaction, whereas on the predicate device the MTT is included in the incubation substrate at the start of the procedure. The final step in the reaction, the formation of the colored formazan, is the same in both devices.

The SPOTCHECK Kit has two additional enzymes in the incubation substrate that are not included on the predicate device. Galactose-6-phosphate dehydrogenase (G6PD) and phosphoglucomutase (PGluM) are normally present in clinical specimens, but may become damaged or destroyed if samples are exposed to excess heat or moisture during handling or if samples are stored at room temperature or above for extended periods of time. The two additional enzymes are included so that samples with degradation of G6PD or PGluM are not incorrectly classified as having deficient GALT activity.

Summary of SPOTCHECK Neonatal GALT Microplate Kit and Predicate Device Comparison of Technological Characteristics

	SPOTCHECK Neonatal GALT Microplate Kit	**Predicate Device**
Specimen collection, handling and storage	Use standardized blood spot collection cards; follow protocol in *CLSI LA4-A5*	Same collection, handling and storage
Specimen	1 x 1/8" punched dried blood spot (DBS)	Same sample size
Incubation	In microplate, on combination incubator/shaker	In covered or sealed microplate, on incubator/shaker
Incubation temperature	37 °C	37 °C
Incubation time	2 hours (120 minutes)	3 hours (180 minutes)
Substrate reagent	Buffered NADP + Gal-1-P + UDP-Glu + G6PD + PGluM	Buffered NADP + tetrazolium salt + Gal-1-P + UDP-Glu + glucose-1,6-diphosphate
Color reagent	Buffered MTT + diaphorase	Buffered diaphorase
Absorbance measurements on microplate reader	600 nm (750 nm reference)	550 or 570 nm
Reporting units	U/g Hb	U/g Hb
Limit of quantitation	0.3 U/g Hb	0.64 U/g Hb
Range	0.3 U/g Hb to 15 U/g Hb	Upper range not stated
Calibration	Liquid NADH standards	Factor multiplication
Clinical classification	Presumptive positive and negative (normal)	Presumptive positive and negative
Quality control material	DBS normal, deficient	DBS normal, deficient

LINEARITY

The assay is non-linear (2nd order regression) in the range of 0.25 to 15 U/g Hb. This correlation was confirmed by adherence to CLSI EP6-A: *Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline*. The calibration curve, established by the use of NADH standards, conforms to a 2nd order regression from 0 to 15 U/g Hb. Results > 15 U/g Hb are reported as such.

ANALYTICAL SENSITIVITY

An overall analytical sensitivity of the assay was determined by adhering to CLSI EP17-A: *Protocols for Determination of Limits of Detection and Limits of Quantitation; Approved Guideline*. The limit of detection (LoD), defined as the lowest amount of analyte in a sample that can be detected (although perhaps not accurately quantifiable), is 0.2 U/g Hb and the limit of quantitation (LoQ) is 0.3 U/g Hb. The LoD is determined consistent with the guidelines in CLSI EP17-A protocol and with proportions of false positives (α) less than 0.3% and false negatives (β) less than 0.3%, based on 300 measurements, consisting of 60 blank and 240 low-level samples; limit of blank (LoB) = 0.08 U/g Hb. The total error (TE, 3xSD) is less than the goal of 0.2 U/g Hb, assuming that there is no bias due to the unavailability of standard reference materials. Therefore, according to the guidelines in CLSI EP17-A, the LoD = LoQ. However, a functional LoQ of 0.3 U/g Hb was established using a criterion of < 20% total imprecision at the LoQ. Neonatal specimens with reported concentrations < 0.3 U/g Hb are reported as such, and can be presumed positive for galactosemia.

AUTOMATED and MANUAL PERFORMANCE COMPARISON

A study was performed to compare the SPOTCHECK GALT Reagent Kit processed using the SPOTCHECK Pro automated platform (configured to precisely automate the manual steps) against the manual method. Newborn patient dried blood spot samples (n = 128), dried blood spot controls manufactured to mimic newborn specimens, as well as dried specimens consisting of mixed adult blood were analyzed using both manual processing and the SPOTCHECK Pro. A total of 216 samples were analyzed using singlicate measurements for both devices. To reduce sources of error not attributed to the different approaches, the same reagent preparations were used, and individual samples were punched and analyzed using each process on the same day. The study was performed over three days.

Regression Results

Linear Regression Statistics	
Multiple R	0.946
R^2	**0.896**
Adjusted R^2	0.895
Standard Error	**0.804**
Observations	**204**

	Coefficients	*Standard Error*	*Lower 95%*	*Upper 95%*
Intercept	**0.393**	0.168	0.063	0.724
X Variable	**0.963**	0.023	0.917	1.01

Statistics include results within claim measuring range only.

This study confirms that manual and automated processing can be expected to provide similar results in screening patients for GALT deficiency.

If manual processing of the reagent kit is intended for use as backup for automated analysis, screening equivalence between the processing methods should be confirmed.

EXPECTED VALUES and DETERMINATION of CLINICAL CUTOFF

An exemplary normal range was established by analyzing 1752 routine samples and 53 known GALT deficient samples (controls, retrospective galactosemic neonates, and galactosemic non-neonates) at a state screening laboratory using the SPOTCHECK Kit (automated on the SPOTCHECK Pro). The same specimens were analyzed using the predicate device.

Data Summary

GALT (Routine)	Predicate Device	SPOTCHECK
Number of Observations	1748	1748
Mean Value Observed	9.4 U/g Hb	7.9 U/g Hb
Standard Deviation	2.2	2.1
Range of the Data	1.4 to 18.5 U/g Hb	2.5 to 14.5 U/g Hb
0.5 Percentile	3.5	3.2
0.25 Percentile	3.2	2.9

Statistics include only results within measuring range of both devices.

Specimens known deficient in GALT yielded results typically below one or both devices' limits of quantitation (49 of 53).

Specimens with results equal to or below the 0.5 and 0.25 percentiles were classified as deficient in GALT activity, or presumptive positive for galactosemia, and require follow-up testing according to institutional, local, state, regional, and/or national guidelines or regulations. Using the same criteria, cutoffs were very similar to the values for presumptive positive and normal GALT activity using the predicate device.

Each laboratory must determine its range of normal and deficient levels of GALT activity, based on its patient population and analytical variables.

CLASSIFICATION of SAMPLES

The performance of the SPOTCHECK Neonatal GALT Microplate Reagent Kit was evaluated against the performance of the predicate device according to CLSI EP9-A2: *Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline — Second Edition.* Patient samples as well as dried blood spot control samples were used in this study.

Screening Results Comparison

Summary of Accuracy (0.5th percentile) {Routine Specimens Only}				
		Reference Test (Predicate Device)		
		Positive	Negative	Total
SPOTCHECK	Positive	8[1]	2	10
	Negative	4	1738	1743
	Total	12	1740	1752
Percent positive agreement (8/12) * 100 = 66.7%				
Percent negative agreement (1738/1740) * 100 = 99.9%				

Summary of Accuracy (0.5th percentile) {All Specimens}				
		Reference Test (Predicate Device)		
		Positive	Negative	Total
SPOTCHECK	Positive	61	2	63
	Negative	4	1738	1743
	Total	65	1740	1805
Percent positive agreement (61/65) * 100 = 93.8%				
Percent negative agreement (1738/1740) * 100 = 99.9%				

Summary of Accuracy (0.25th percentile) {Routine Specimens Only}				
		Reference Test (Predicate Device)		
		Positive	Negative	Total
SPOTCHECK	Positive	4[2]	1	5
	Negative	1	1746	1747
	Total	5	1747	1752
Percent positive agreement (4/5) * 100 = 80.0%				
Percent negative agreement (1746/1747) * 100 = 99.9%				

Summary of Accuracy (0.25th percentile) {All Specimens}				
		Reference Test (Predicate Device)		
		Positive	Negative	Total
SPOTCHECK	Positive	57	1	58
	Negative	1	1746	1747
	Total	58	1747	1805
Percent positive agreement (57/58) * 100 = 95.2%				
Percent negative agreement (1746/1747) * 100 = 99.9%				

[1] Routine neonatal screening by the state DOH classified all but one of these specimens (as well as the specimens classified as negative) to be presumptive negative for galactosemia. The laboratory classified the one specimen as having partial GALT activity.

[2] Routine neonatal screening by the state DOH classified all but one of these specimens (as well as the specimens classified as negative) to be presumptive negative for galactosemia. The laboratory classified the one specimen as having partial GALT activity.

Screening Using Manual Processing

An internal study was performed for manual comparison to the predicate device. Newborn patient dried blood spot samples (n = 247), dried blood spot controls with newborn hematocrit, and dried specimens consisting of mixed adult blood were analyzed using both the SPOTCHECK Kit and the predicate device. A total of 292 samples were analyzed using singlicate measurements for both devices. A population of specimens that provided a large number of low GALT activity results was analyzed to ensure a high number of relevant screening classification comparisons.

GALT {All Specimens}	Predicate Device	SPOTCHECK
No. of Observations (in range)	265	265
Mean Value	4.8 U/g Hb	5.2 U/g Hb
Standard Deviation	2.4	2.5
Range of the Data	0.6 to 12.6 U/g Hb	1.1 to 14.3 U/g Hb

Statistics include only results within measuring range of both devices.

Deficient GALT Activity (Presumptive Positive)	≤ 2.3 U/g Hb	≤ 3.2 U/g Hb (0.5^{th} percentile) and ≤ 2.9 U/g Hb (0.25^{th} percentile)
Normal GALT Activity (Negative)	> 2.3 U/g Hb	> 3.2 U/g Hb (0.5^{th}) and > 2.9 U/g Hb (0.25^{th})

Summary of Accuracy (0.5^{th} percentile cutoff) {All specimens}				
		Predicate Device		
		Positive	Negative	Total
SPOTCHECK	Positive	60	27	87
	Negative	2	203	205
	Total	62	230	292
Percent positive agreement: (60/62) = 96.7%				
Percent negative agreement: (203/230) = 88.3%				

Summary of Accuracy (0.25^{th} percentile) {All Specimens}				
		Predicate Device		
		Positive	Negative	Total
SPOTCHECK	Positive	58	16	74
	Negative	4	214	218
	Total	62	230	292
Percent positive agreement: (58/62) = 93.5%				
Percent negative agreement: (214/230) = 93.0%				

The SPOTCHECK GALT *in vitro* diagnostic kit demonstrated a high degree of correlation to specimens classified positive by the predicate device. Additionally, 10 specimens known to be deficient in GALT activity (analyzed in an unbiased manner) were correctly classified.

This evaluation complements the study demonstrating equivalent performance between manual and automated processing. Combined, they demonstrate safety and effectiveness of the new GALT screening method, using manual or automated specimen analysis.

PRECISION PERFORMANCE

Within-run and total precision for the SPOTCHECK Kit were determined according to CLSI EP5-A2: *Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline — Second Edition.* Samples at 4 different levels of GALT activity were analyzed using 16 replicates on 1 run per day for 5 days (2 distinct calibration curves on 2 plates); a total of 80 data points at each level were collected. Within-run and total precision using the *predicate device* for normal GALT activity levels was determined by analyzing samples in duplicate during 10 separate runs (data reported below was copied from product insert). The method used to determine precision of deficient and partial activity GALT samples in the predicate device was not stated.

Within-Run Precision, S_r

SPOTCHECK Neonatal GALT Kit

(Manual, n = 80)

Activity (U/g Hb)	Deficient	Partial	Near cutoff	Normal
Mean	0.45	1.3	2.4	6.7
S.D.	0.037	0.087	0.20	0.55
C.V.	8.1%	6.5%	8.3%	8.2%

(Automated on the SPOTCHECK Pro, n = 80)

Activity (U/g Hb)	Deficient	Partial	Near cutoff	Normal
Mean	0.60	1.3	2.4	6.1
S.D.	0.046	0.081	0.16	0.40
C.V.	7.8%	6.2%	6.7%	6.6%

Predicate Device

(Manual, n = 20)

Activity (U/g Hb)	Normal	Normal	Normal
Mean	3.5	3.6	5.0
S.D.	0.15	0.27	0.37
C.V.	4.3%	12%	7.4%

Total Precision, S_T

SPOTCHECK Neonatal GALT Kit

(Manual, n = 80)

Activity (U/g Hb)	Deficient	Deficient	Near cutoff	Normal
Mean	0.45	1.3	2.4	6.7
S.D.	0.05	0.12	0.22	0.65
C.V.	11%	9.2%	9.2%	9.7%

Total Precision, S_T (continued)

(Automated on the SPOTCHECK Pro, n = 80)

Activity (U/g Hb)	Deficient	Partial	Near cutoff	Normal
Mean	0.60	1.3	2.4	6.1
S.D.	0.063	0.095	0.17	0.41
C.V.	11%	7.3%	7.1%	6.7%

Predicate Device

(Manual, n = 20)

Activity (U/g Hb)	Partial[ii]	Normal	Normal	Normal
Mean	1.8	3.5	3.6	5.0
S.D.	0.45	0.37	0.43	0.40
C.V.	23%	11%	12%	8.0%

[ii](Number of samples (n) is not reported.)

The results of the precision study demonstrate that the SPOTCHECK Neonatal GALT Microplate Reagent Kit, at a minimum, exhibits comparable precision performance to that reported in the predicate device insert. Additionally, performance is similar whether the SPOTCHECK kit is processed manually or with automation.

ANALYTICAL SPECIFICITY

The study of potential interfering substances when using the SPOTCHECK Neonatal GALT Microplate Reagent Kit was carried out according to CLSI EP7-A2: *Interference Testing in Clinical Chemistry; Approved Guideline — Second Edition.*

Interference Evaluated	SPOTCHECK Neonatal GALT Microplate Kit	Predicate Device
γ globulin (protein)	Up to 6000 mg/dL showed no statistically significant interference; minor increases in GALT were observed near the cutoff, but a deficient neonate would not be classified as normal	up to 2500 mg/dL showed no significant interference
Albumin (protein)	Up to 6000 mg/dL showed no statistically significant interference; minor increases in GALT were observed near the cutoff, but a deficient neonate would not be classified as normal	not evaluated
Bilirubin, conjugated	Up to 28.8 mg/dL showed no statistically or clinically significant interference	up to 40 mg/dL showed no significant interference
Bilirubin, unconjugated	Up to 20 mg/dL showed no	up to 40 mg/dL showed

	statistically or clinically significant interference	no significant interference
Hemoglobin (Hb)	Up to 200 mg/dL showed a statistically significant decrease in GALT activity, which could result in a false positive near the cutoff	not evaluated
Triglycerides	Up to 3270 mg/dL showed no statistically or clinically significant interference	up to 1000 mg/dL showed no significant interference
Sulfamethoxazole (SMX)	Up to 400 µg/mL showed no statistically or clinically significant interference	not evaluated
Trimethoprim (TMP)	Up to 40 µg/mL showed no statistically or clinically significant interference	not evaluated

Contributions from Hematocrit

To determine any possible effects on the performance of the Astoria-Pacific, Inc. SPOTCHECK Neonatal GALT Microplate Reagent due to varying blood hematocrit, three blood spot samples were manufactured, one with deficient GALT, one near the clinical cutoff, and one with normal GALT. Within each of the three blood spot samples, three different levels of hematocrit (45%, 55% and 65%) were achieved by adjusting the quantity of red blood cells prior to spotting on blood spot collection paper.

Hematocrit %	Deficient (n = 6)	Near Cutoff (n = 6)	Normal (n = 6)
45	0.43 U/g Hb	2.4 U/g Hb	5.4 U/g Hb
55	0.55 U/g Hb	2.7 U/g Hb	6.9 U/g Hb
65	0.72 U/g Hb	3.3 U/g Hb	8.3 U/g Hb

GALT activity resides in the red blood cells, so it is expected that varying hematocrit will lead to varying GALT response. Samples with lower hematocrit levels had lower GALT activity and samples with higher hematocrit levels had GALT activity. Differences in hematocrit had a statistically significant effect on samples with low GALT activity, however there is no indication that a sample deficient in GALT activity would be misclassified as normal (false negative) due to varying hematocrit levels.

7. Determination of Substantial Equivalency

Based on the performance characteristics and comparison data, the SPOTCHECK Kit is safe, effective, and substantially equivalent to the legally-marketed predicate device. The indications for use are essentially the same for the SPOTCHECK Neonatal GALT Microplate Reagent Kit and the predicate device. Technological characteristics are very similar to the predicate device and there is sufficient evidence that demonstrates that the differences do not adversely affect the safety and effectiveness of the SPOTCHECK Kit.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

JUL 15 2011

Astoria-Pacific, Inc.
c/o Mr. Jason C. Reynolds
Director of Research & Development
15130 SE 82nd Dr.
Clackamas, OR 97015

Re: k102643
Trade Name: SPOTCHECK Neonatal GALT Microplate Reagent Kit, SPOTCHECK Pro
Regulation Number: 21 CFR §862.1315
Regulation Name: Galactose-1-Phosphate Uridyl Transferase test system
Regulatory Class: Class II
Product Codes: KQP, JJQ
Dated: July 8, 2011
Received: July 11, 2011

Dear Mr. Reynolds:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Courtney Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number: k102643

Device Name: SPOTCHECK® Neonatal GALT Microplate Reagent Kit

Indications for Use:

The SPOTCHECK Neonatal GALT Microplate Reagent Kit is for the quantitative determination of galactose-1-phosphate uridyltransferase, EC 2.7.7.12 (GALT), activity in whole blood saturated filter paper disks, using a microplate absorbance reader. Measurements of GALT enzyme activity are used primarily in the diagnosis and treatment of the hereditary disease galactosemia. This method is intended for in vitro diagnostic use as an aid in neonatal screening for decreased levels of GALT enzyme activity, and not for monitoring purposes.

This device is intended for use by trained, qualified laboratory personnel.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K102643

Indications for Use Form

510(k) Number: k102643

Device Name: SPOTCHECK Pro™

Indications for Use:

The SPOTCHECK Pro is used for automated sample processing in the application of *in vitro* diagnostic assays. Specimens containing patient bodily substances are introduced and analyzed in microtiter plates using qualitative/quantitative determination through absorbance measurements.

This device and assays are intended for use by trained, qualified laboratory personnel.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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